



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	MATHIESEN, Iacob, et al.	Examiner:	BOCKELMAN, Mark
Serial No.:	10/620,271	Group Art Unit:	3762
Filed:	14 July 2003	Docket:	GTI-5000-CT3
Title:	METHOD FOR MUSCLE DELIVERY OF DRUGS, NUCLEIC ACIDS AND OTHER COMPOUNDS		

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed please find Form SB08, which Applicants submit pursuant to 37 C.F.R. § 1.56 and 37 C.F.R. §§ 1.97 *et. seq.*, along with a copy of each of the previously uncited non-patent references listed on Form SB08, for consideration in connection with the captioned application. A check including payment of the requisite fee is included herewith.

Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form SB08 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the attached Form SB08 be initialed by the Examiner to inductate consideration of each of the listed references, and that the initialed form then be returned to Applicants with the next official communication.

05/12/2005 CCHAU1 00000006 10620271

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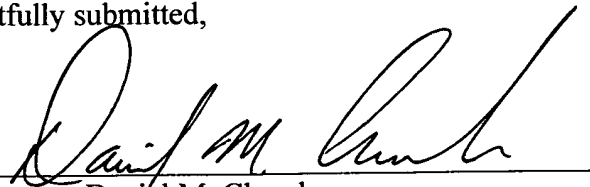
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The Examiner is invited to contact the undersigned at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

Date May 9, 2005  
BioTechnology Law Group  
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By

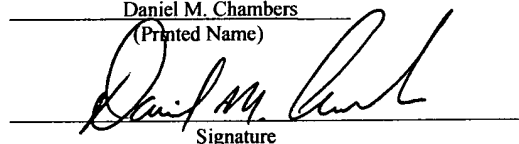


Daniel M. Chambers  
Reg. No. 34,561

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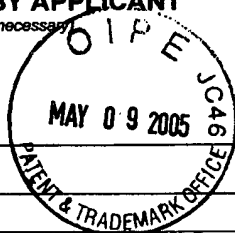
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STATEMENT BY APPLICANT**

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Complete If Known

Application Number	10/620,271
Filing Date	14 July 2003
First Named Inventor	Mathiesen, Iacob
Group Art Unit	3762
Examiner Name	Bockelman, Mark

Sheet 1 of 4

Attorney Docket No: GTI-5000-CT3

**US PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US 5,501,662	03-26-1996	Hofmann	
	A2	US 5,468,223	11-21-1995	Mir	
	A3	US 5,389,069	02-14-1995	Weaver	
	A4	US 5,318,514	06-07-1994	Hofmann	
	A5	US 5,304,120	04-19-1994	Crandell, et al.	
	A6	US 5,273,525	12-28-1993	Hofmann	
	A7	US 5,993,434	11-30-1999	Dev, et al.	
	A8	US 5,944,710	08-31-1999	Dev, et al.	
	A9	US 5,964,726	10-12-1999	Korenstein, et al.	
	A10	US 5,810,726	09-22-1998	Hofmann	
	A11	US 5,702,359	12-30-1997	Hofmann, et al.	
	A12	US 6,009,347	12-28-1999	Hofmann	
	A13	US 6,041,252	03-21-2000	Walker, et al.	
	A14	US 5,674,267	10-07-1997	Mir, et al.	
	A15	US 5,501,662	03-26-1996	Hofmann	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
	A16	WO 95/23211	08-31-1995	Korenstein, et al.		
	A17	WO 99/01157	01-14-1999	Rhone-Poulenic, et al.		
	A18	WO 98/27966	07-02-1998	Piechaczyk, et al.		

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	A19	WO 98/43702	10-08-1998	Lomo, et al.		
	A20	WO 00/45823	08-10-2000	Shelby, et al.		

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A21	Aihara, et al., "Gene Transfer into Muscle by Electroporation In Vivo", <i>Nature Biotechnology</i> , (1998), 867-870, Vol. 16	
	A22	Bachy, Monique, et al: "Electric Pulses Increase The Immunogenicity Of An Influenza DNA Vaccine Injected Intramuscularly In The Mouse" <i>Vaccine</i> , (2001), 1688-1693, 19:13-14, Elsevier Science Ltd, <a href="http://www.elsevier.com/locate/vaccine">www.elsevier.com/locate/vaccine</a>	
	A23	Bhatt, D.; et al., "Rhabdomyolysis Due to Pulsed Electric Fields" <i>Plastic and Reconstructive Surgery</i> , (1990), 1-11, 86:1	
	A24	Block, T.A., et al., "Nonthermally Mediated Muscle Injury and Necrosis in Electrical Trauma", <i>Journal of Burn Care &amp; Rehabilitation</i> , (1995), 581-588, 16:6	
	A25	Collas, P., et al., "The Nuclear Localization Sequence of the SV40 T Antigen Promotes Transgene Uptake and Expression in Zebrafish Embryo Nuclei", <i>Transgenic Research</i> , (1996), 451-458, Vol. 5	
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	A27	Davis, H.L., et al., "Direct Gene Transfer into Skeletal Muscle in Vivo: Factors Affecting Efficiency of Transfer and Stability of Expression", <i>Human Gene Therapy</i> , (1993), 151-159, Vol. 4	
	A28	Heller, R., et al., "In Vivo Gene Electroinjection and Expression in Rat Liver" (1996), FEBS Letter, 225-228, Vol. 389	
	A29	Hiroyuki, A., et al., "Gene Transfer into Muscle by Electroporation In Vivo", <i>Nature Biotechnology</i> , (1998), 867-870, Vol. 16	
	A30	Hoffman, G.A., "Cells in Electric Fields", <i>In Electroporation and Electrofusion in Cell Biology</i> , ed., Neuman, E.; Sowers, A.E. & Jordan, C.A., (1989), 3849-407, Plenum Publishing Corporation	
	A31	Katsumi, et al., "Humoral and Cellular Immunity to an Encoded Protein Induced by Direct DNA Injection", <i>Human Gene Therapy</i> , (1994), 1335-1339, Vol. 5	
	A32	Kadowaki, Shin-Etsu, et al: "Protection Against Influenza Virus Infection in Mice Immunized By Administration Of Hemagglutinin-Expressing DNAs With Electroporation" <i>Vaccine</i> , (2000), 2779-2788, vol. 18, Elsevier Science Ltd., <a href="http://www.elsevier.com/locate/vaccine">www.elsevier.com/locate/vaccine</a>	
	A33	Le Borgne, Sylvie, et al., "In Vivo Induction Of Specific Cytotoxic T Lymphocytes In Mice And Rhesus Macaques Immunized With DNA Vector Encoding An HIV Epitope Fused With Hepatitis B Surface Antigen." <i>Virology</i> , (1998), 304-315, 240:2, Article No.: VY978942, Academic Press	
	A34	Lee, R.C., et al., "Transient and Stable Ionic Permeabilization of Isolated Skeletal Muscle Cells After Electrical Shock", <i>Journal of Burn Care &amp; Rehabilitation</i> , (1993), 528-540, 14:5	
	A35	Lim, et al., "Potentiation of Antigen-Specific, Th1 Immune Responses by Multiple DNA Vaccination with an Ovalbumin/Interferon- $\gamma$ Hybrid Construct", <i>Immunology</i> , (1998), 135-141, Vol. 94	

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Sheet 3 of 4

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	A36	Manthorpe, M., et al., "Gene Therapy by Intramuscular Injection of Plasmid DNA: Studies on Firefly Luciferase Gene Expression in Mice", <i>Human Gene Therapy</i> , (1993), 419-431, Vol. 4				
	A37	Martinez, et al., "Combining DNA and Protein Vaccines for Early Life Immunization Against Respiratory Syncytial Virus in Mice", <i>European Journal of Immunology</i> , (1999), 3390-3400, 29:10 Abstract				
	A38	Mathiesen, I.: "Electroporation of Skeletal Muscle Enhances Gene Transfer In Vivo." <i>Gene Therapy</i> , (1999), 508-514, 6:4, Stockton Press, <a href="http://www.stockton.press.co.uk/qt">www.stockton.press.co.uk/qt</a>				
	A39	Mendiratta, Sanjeev Kumar, et al.: "Therapeutic tumor immunity induced by polyimmunization with melanoma antigens gp100 and TRP-2" <i>Cancer Research</i> , (2001), 859-863, 61:3,				
	A40	Wiklavcic, D., et al., "The Importance of Electric Field Distribution for Effective In Vivo Electroporation of Tissues", <i>Biophysical Journal</i> , (1998), 2152-2158, Vol. 74				
	A41	Nishi, T., et al., "High-Efficiency In Vivo Gene Transfer Using Intraarterial Plasmid DNA Injection Following In Vivo Electroporation", <i>Cancer Research</i> , (1996), 1050-1055, Vol. 56				
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	A43	Potter, H., "Electroporation in Biology: Methods, Applications, and Instrumentation", [Review], <i>Analytical Biochemistry</i> , (1998), 361-373, Vol. 174				
	A44	Prausnitz, M.R., et al., "Electroporation of Mammalian Skin: A Mechanism of Enhance Transdermal Drug Delivery", <i>Proc. Natl. Acad. Sci. USA</i> , (1993), 10504-10508, Vol. 90				
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	A46	Rols, M.P., et al., "Electroporation of Mammalian Cells: Quantitative Analysis of the Phenomenon", <i>Biophysical Journal</i> , (1990), 1089-1098, Vol. 58				
	A47	Rols, M.P., et al., "In Vivo Electrically Mediated Protein and Gene Transfer in Murine Melanoma", <i>Nature Biotechnology</i> , (1998), 168-171, Vol. 16				
	A48	Selby, Mark, et al., "Enhancement of DNA vaccine potency by electroporation in vivo." <i>Journal Of Biotechnology</i> , (2000), 147-152, 83:1-2, Elsevier Science B.V., <a href="http://www.elsevier.com/locate/biotech">www.elsevier.com/locate/biotech</a>				
	A49	SIN, Jeong-Im, et al., "DNA priming-protein boosting enhances both antigen-specific antibody and Th1-type cellular immune responses in a murine herpes simplex virus-2 gD vaccine model", <i>DNA And Cell Biology</i> , (1999), 771-779, 18:10				
	A50	Smith, L.C., et al., "Advances In Plasmid Gene Delivery And Expression In Skeletal Muscle" <i>Curr. Opin. Mol. Ther.</i> , (2000), 150-154, Vol. 39				
	A51	Tekle, E., et al., "Electroporation by Using Bipolar Oscillating Electric Field: An Improved Method for DNA Transfection of NIH 3T3 Cells", <i>Pro. Natl. Acad. Sci. USA</i> , (1991), 4230-4234, Vol. 88				
	A52	"The Effects of a Single High Voltage Electrical Stimulation with an Anticancer Drug in In Vivo Growing Malignant Tumors", <i>Japanese Journal of Surgery</i> , (1990), 197-204, 20:2				
	A53	Widera, G., et al., "Increased DNA Vaccine Delivery and Immunogenicity by Electroporation In Vivo", <i>The Journal of Immunology</i> , (2000), 4635-4640, Vol. 164				
	A54	Wolf, H., et al., "Control by Pulse Parameters of Electric Field-Mediated Gene Transfer in Mammalian Cells", <i>Biophysical Journal</i> , (1994), 524-531, Vol. 66				

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<b>First Named Inventor</b>	Mathiesen, Jacob
<b>Group Art Unit</b>	3762
<b>Examiner Name</b>	Bockelman, Mark
<b>Attorney Docket No: GTI-5000-CT3</b>	

Sheet 4 of 4

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	A55	Wolff, J.A., et al., "Long-Term Persistence of Plasmid DNA and foreign Gene Expression in Mouse Muscle", <i>Human Molecular Genetics</i> , (1992), 363-369, 1:6				
	A56	Wolff, J.A., et al., "Conditions Affecting Direct Gene Transfer into Rodent Muscle In Vivo", <i>Biotechniques</i> , (1991), 474-485, 11:4, XP000973460				
	A57	Zewert, Thomas E., et al., "Creation of Transdermal Pathways for Micromolecule Transport by Skin Electroporation and a Low Toxicity, Pathway Enlarging Molecule", <i>Bioelectrochemistry and Bioenergetics</i> , (1999), 11-20, 49:1, Elsevier Science S.A., <a href="http://www.elsevier.com/locate/biochem">www.elsevier.com/locate/biochem</a>				
	A58	Zhu, et al., "DNA fusion vaccines against B-cell tumors," <i>Trends Mol Med</i> 7:566-572 (2001)				
	A59	Zucchelli, S., et al., "Enhancing B- and T-Cell Immune Response to a Hepatitis C Virus E2 DNA Vaccine by Intramuscular Electrical Gene Transfer". <i>Journal of Virology</i> , (2000), 11598-11607, 74:24, American Society for Microbiology				

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